JAN - 3 2005

K042792 (1 of 2)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of 21 CFR 807.92:

Submitter: Insulet Corporation
9 Oak Park Drive
Bedford, MA 01730-1413
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Contact: Mr. A. Arthur Rankis
Director of Quality and Regulatory Affairs
(781) 457-4743

Date Prepared: October 6, 2004

Trade Name: iXL-II Diabetes Management System with Blood Glucose Measurement

Common Name: External insulin infusion Pump and blood glucose monitor

Classification Name: Infusion Pump 21CFR §880.5725

Legally Marketed Devices to which we are claiming equivalence:

The iXL-II Diabetes Management System with Blood Glucose Measurement is substantially equivalent to the iXL Diabetes Management System and to the TheraSense FreeStyle Blood Glucose Monitor.

Intended Use:

The iXL-II Diabetes Management System with Blood Glucose Measurement is intended for continuous, subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro). It is available only by or on the order of a physician.

Summary Description of the iXL-II Diabetes Management System

The iXL-II Diabetes Management System has two (2) components: a Remote Controller with integral blood glucose monitoring technology, and an insulin infusion Pod. Accessories include:

- Batteries and IFU packaged with the Remote Controller
- A fill syringe and fill needle packaged with each Pod.

Other accessories for use with the iXL-II Diabetes Management System will be available from Insulet Corporation. Accessories will include batteries, a Carry Case, a TheraSense FreeStyle Lancing Device, TheraSense FreeStyle lancets, TheraSense FreeStyle test strips, TheraSense FreeStyle Control Solution, commercially available site prep and adhesive removal wipes, etc. The IFU for the iXL-II Diabetes Management System will specify the use of only the TheraSense FreeStyle components for use with the iXL-II blood glucose measurement function.

The Remote Controller is a hand held, battery-operated device, with 10 functional buttons, an electro-luminescent (EL) backlit liquid crystal display (LCD) and BG Test Strip Reader. The device provides audio alarms, alerts and reminders.

The Pod is activated and controlled exclusively through the use of the Remote Controller. The Pod and Remote Controller interact wirelessly using secure, bi-directional radio frequency (RF).

The Pod is a microprocessor-controlled device worn directly on the body in the same manner and general locations as a conventional insulin infusion set. The Pod will deliver insulin based on the users custom programmed basal rate and bolus doses for up to 72 hours and provides audio alarms, alerts and reminders.

Comparison of the New Device to the Predicate Devices

The iXL-II Diabetes Management System with Blood Glucose Measurement is substantially equivalent to the iXL Diabetes Management System and to the TheraSense FreeStyle Blood Glucose Monitor

Conclusion:

The modifications discussed in this submission raise no new questions regarding the safety and effectiveness of the iXL-II Diabetes Management System with Blood Glucose Measurement as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2005

Mr. A. Arthur Rankis
Director of Quality and Regulatory Affairs
Insulet Corporation
9 Oak Park Drive
Bedford, Massachusetts 01730-1413

Re: K042792
Trade/Device Name: iXL-I I Diabetes Management System with Blood Glucose Measurement
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 6, 2004
Received: October 7, 2004

Dear Mr. Rankis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Juliette McChiu M.D.
FOR DR. CHIU LIN

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known) K042792

Device Name iXL-II Diabetes Management System with Blood Glucose Measurement

Indications for Use Intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro).

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzette Y. McBurney M.D.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042792